P.E.T.Net® Pharmaceuticals, Inc.
Fueling the Power of P.E.T.

June 12, 2002

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

VIA Electronic Submission

RE: Docket No. 98D-0266
Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Availability [67 **Federal Register** 15404]

ERRATUM

Dear Sir/Madam:

In a letter dated June 5, 2002, PETNet® Pharmaceuticals, Inc. (PETNet) supplied comments on the above referenced docket. A review of this letter has revealed an omission in the section entitled "Microbiological Control of Aseptic Processing and Sterilizing Filtration." This section is located near the bottom of page 6. We apologize for this error and ask that you accept the following correction to our original letter.

Microbiological Control of Aseptic Processing and Sterilizing Filtration

Lines 995 through 998 of the draft guidance document discuss aseptic processing in the production of PET radiopharmaceuticals.

Comment

We believe that the only aseptic process pertinent to the production of a commercial PET radiopharmaceutical (e.g., [^{18}F]FDG) is the assembly of pre-sterilized components to form a vial assembly used in the final filtration of a PET radiopharmaceutical. We believe that the aseptic transfers used in the production of PET radiopharmaceuticals are different from aseptic processing. Injectable PET products are suitable for human use only after passage through a sterilizing filter and immediate transfer into a sterile vial. This closed process typically occurs through a needle inserted into a pre-sterilized, pre-assembled, commercially available vial. This differs substantially from typical aseptic processing operations wherein numerous vials and closures are sterilized separately, then the product is filtered into an open vial and the closure then secured in place. We believe that the level of aseptic process control and validation should reflect this environment.

Sincerely,

Steve Zigler

Steve Zigler, Ph.D.
Director, Quality and Regulatory Affairs